## THINK IN SERVICES. U.S.

## **DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service
Centers for Disease Control and Prevention (CDC)
Atlanta, GA 30333

To Whom It May Concern:

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) are agencies of the U.S. Government and are conducting medical record review of persons who have recently received a vaccine(s) and have reported health problems. CDC and FDA are public health authorities as defined by the Health Insurance Portability and Accountability Act (HIPAA), Standards for Privacy of Individually Identifiable Health Information; Final Rule (Privacy Rule) [45 CFR §164.501]. Pursuant to 45 CFR §164.512(b) of the Privacy Rule, covered entities such as your organization may disclose, without individual authorization, protected health information to public health authorities " . . . authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions . . . "

The CDC and the FDA are conducting surveillance for vaccine associated adverse events through the Vaccine Adverse Events Reporting System (VAERS), a public health activity as described by 45 CFR § 164.512(b), and authorized by 42 USC 300aa-25. The information being requested represents the minimum necessary to carry out the public health purposes of this project pursuant to 45 CFR §164.514(d) of the Privacy Rule.

Please mail all requested medical records to VAERS at: VAERS, P.O. Box 1100, Rockville, MD 20849-1100.

Medical records can also be faxed to VAERS at 1-877-721-0366.

If you have questions or concerns, or want further information about VAERS, you can visit the VAERS website at www.vaers.hhs.gov or send an e-mail to <a href="mailto:info@vaers.org">info@vaers.org</a>. You can also contact VAERS by calling 1-800-822-7967.

If your facility has a designated point of contact for HIPAA and related issues, this is the best source to answer your questions about providing medical records to VAERS or to obtain further information on HIPAA. For additional information, please see the guidance from CDC and the U.S. Department of Health and Human Services on the HIPAA Privacy Rule and public health, available at <a href="https://www.cdc.gov/mmwr/PDF/wk/su5201.pdf">www.cdc.gov/mmwr/PDF/wk/su5201.pdf</a>.

Adapted from Centers for Disease Control and Prevention. HIPAA Privacy Rule and public health: guidance from CDC and the U.S. Department of Health and Human Services. MMWR 2003;52(Supl): Appendix B (www.cdc.gov/mmwr/PDF/wk/su5201.pdf)

Sincerely,

Records Coordinator at VAERS